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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,621

12/30/2003

Ali R. Rezai

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/749,621

Applicant(s)

REZAI ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 10-12, 15, 18-23 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 10-12, 15, 18-23 and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

Although the Applicant has amended the claims to include previously allowable subject matter, due to newly discovered reference(s) to Singhal et al. (US Patent Publication 20050004637 A1) and Mogg (PCT/GB03/00539, International Publication Number WO 03/068304 A1), the allowability has been revoked. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 12, 22, 36 and 41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. What makes "distinct" or "different" sections of the leads is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 1, 12, 22, 36 and 41 recite the limitations "distinct sections" in claim 1 and "different sections" in claims 12, 22, 36 and 41. There is insufficient antecedent basis for this limitation in the claim. The Applicant does not disclose in the specification what makes the sections of the lead "different" or "distinct" sections.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 1, 22, 36, 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant, in claims 1, 22, 36 and 41, does not positively recite the inclusion of a lead with the system for retaining a lead, but merely inferentially includes the use of a lead. It is unclear whether the Applicant intends to claim the use of a specific lead with the retaining device or is merely claiming the retaining device.

2. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 recites the limitation "wherein the change in temperature decrease" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, since there is no positive recitation for a temperature change.

Claim Rejections - 35 USC § 102

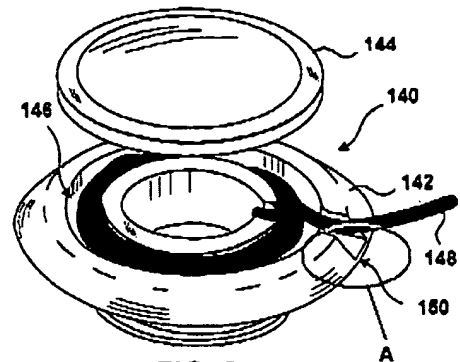
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 12, 15, 20-23, 36-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Singhal et al. (US Patent Publication 20050004637 A1). Singhal et al. discloses a burr hole cap with a lead management system as depicted in figure 8.

As to claim 12, the ring member 142 is considered to be a flange. The examiner considers the walls of groove or exit 150 to be tabs. As depicted in the replica of figure 8 to the right, the wall label "A" is one of the tabs. The two tabs, or walls create the exit 150. Furthermore, the examiner also considers the inner core of the burr hole cap to also possess tabs, with similar groove/tab structure as stated above.



As to claims 12 and 22-23, Additionally there is a plurality of grooves, the inside groove 146 and exit 150, which the examiner considers to be a groove. Also, the cut out in the core of the burr hole cap, where the lead enters the cap is also considered to be a groove.

As to claim 15, since the groove extends from the core of the burr hole ring to the external ring member, the examiner considers the groove to be a "spiral groove" since the groove "extends for the aperture to at least one outlet periphery of the outside surface of the burr ring".

As to claim 20, Singhal et al. discloses on page 5, paragraph 64, "Ring member 142, cover member 144 or both can be constructed from a protective material that would resist damage in the event the incision should cut across burr hole cover 140".

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Therefore, since the protective material would resist damage, the examiner considers it to be "resilient material".

As to claim 21, the lead can be coiled in a plurality of different coiling configurations since the lead can be coiled around the core, in a lateral manner, or coiled from the core to the outer peripheral of the ring, in a horizontal manner.

As to claims 36 and 41, the recitation of "in configuration that reduces a change in temperature at a contact of the lead when the patient is undergoing an MRI procedure" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). (see MPEP 2111.02). The method does not include a step for placing the excess lead "in configuration that reduces a change in temperature at a contact of the lead when the patient is undergoing an MRI procedure". Therefore since this limitation was only placed in the preamble, the examiner has not considered the limitation.

As to claim 39, as the number of loops of the excess lead is coiled around the burr hole increases, there would necessarily be a resistance to a change in temperature, or a decrease in the change of temperature, due to the insulative property of the lead.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 1-5, 7-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singhal et al. (US Patent Publication 20050004637 A1). Singhal et al. discloses the claimed invention except for the grooves having a width less than the diameter of each lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the grooves as taught by Singhal et al. with a grooves less than the diameter of the leads to hold the leads since it was known in the art that a reduced groove would enable the pinching or locking of a lead to prevent movement of the lead while positioned within the skull.

2. Claim 1-5, 7-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mogg (PCT/GB03/00539, International Publication Number WO 03/068304 A1). Mogg discloses a catheter clamp and a clamping means with a retainer formed from several grooves. Mogg discloses the claimed invention except for the placement of the apparatus into a burr hole in the patient's skull to secure a lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the clamping system as taught by Mogg with a lead for placement in a burr hole, since such a modification would enable the leads to be locked in a low profile design to enable a streamline clamping to prevent movement of a lead in the skull.

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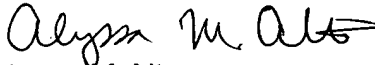
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pianca et al. (US 7004948 B1) discloses a burr hole plug.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762

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GEORGE R. EVANISKO
PRIMARY EXAMINER

5/29/7